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DOCKET NO.: P0453.70116US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sanghvi et al.
Serial No.: 10/821,809
Confirmation No.: Not Yet Assigned
Filed: April 8, 2004
For: COMINATION THERAPY FOR CONSTIPATION

Examiner: Not Yet Assigned
Art Unit: Not Yet Assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16 day of June, 2004.

Kristin J. Ketelhut
Kristin J. Ketelhut

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Sanghvi et al., Applicant

By: Edward R. Gates
Edward R. Gates, Reg. No.: 31,616
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Docket No. P0453.70116US01
Date: June 16, 2004
x07/08/04x



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Kristin J. Ketelhut

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing date of a National Application other than a continued prosecution application under 37 C.F.R. §1.53(d).

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
P0453.70109US00	10/163,482	June 5, 2002	Moss et al.
P0453.70110US00	10/278,630	October 23, 2002	Foss et al.
P0453.70110US01	10/779,129	February 12, 2004	Foss et al.
P0453.70112US01	10/821,813	April 8, 2004	Boyd et al.
P0453.70113US00	10/357,669	February 4, 2003	Foss et al.
P0453.70113US01	10/779,128	February 12, 2004	Foss et al.
P0453.70113US02	10/778,268	February 12, 2004	Foss et al.
P0453.70113US03	10/785,320	February 12, 2004	Foss et al.
P0453.70113US04	10/785,668	February 24, 2004	Foss et al.
P0453.70114US00	10/358,560	February 5, 2003	Foss et al.
P0453.70115US01	10/821,811	April 8, 2004	Sanghvi et al.

The following are remarks concerning the other information cited:

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

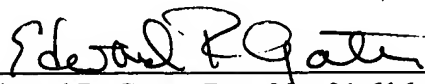
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Sanghvi et al., *Applicant*

By: 
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FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO.: 10/821,809		ATTY. DOCKET NO.: P0453.70116US01	
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			GROUP ART UNIT: Not Yet Assigned		EXAMINER: Not Yet Assigned	
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U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	2001/0018413	A1	Crain, <i>et al.</i>	08-30-2001
	A2	2002/0028825	A1	Foss, <i>et al.</i>	03-07-2002
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		Office/ Country	Number	Kind Code			
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	B2	CA	1,315,689		The University of Chicago	04-06-1993	
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	B13	WO	95/31985	A2	Minoia, <i>et al.</i>	11-30-1995	
	B14	WO	97/33566		Alza Corp.	09-18-1997	
	B15	WO	98/25613		Klinge Pharma GmbH	06-18-1998	Yes
	B16	WO	01/13909	A2	Critical Care Pharm.	03-01-2001	
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OTHER ART — NON PATENT LITERATURE DOCUMENTS

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	C1	AKINBAMI et al., Effect of a peripheral and a central acting opioid antagonist on the testicular response to stress in rats. <i>Neuroendocrinology</i> . 1994 Apr;59(4):343-8.	
	C2	AMIN et al., Efficacy of methylnaltrexone versus naloxone for reversal of morphine-induced depression of hypoxic ventilatory response. <i>Anesth Analg</i> . 1994 Apr;78(4):701-5.	
	C3	AMIR, Naloxone improves, and morphine exacerbates, experimental shock induced by release of endogenous histamine by compound 48/80. <i>Brain Res</i> . 1984 Apr 9;297(1):187-90.	
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	C5	ARGENTIERI et al., Interaction of the opiate antagonist, naltrexone methyl bromide, with the acetylcholine receptor system of the motor end-plate. <i>Brain Res</i> . 1983 Oct 31;277(2):377-9.	
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FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO.: 10/821,809		ATTY. DOCKET NO.: P0453.70116US01	
			FILING DATE: April 8, 2004		CONFIRMATION NO.: Not Yet Assigned	
			APPLICANT: Sanghvi et al.			
			GROUP ART UNIT: Not Yet Assigned		EXAMINER: Not Yet Assigned	
Sheet	6	of	6			

	C106	YUAN et al., Methylnaltrexone prevents morphine-induced delay in oral-cecal transit time without affecting analgesia: a double-blind randomized placebo-controlled trial. Clin Pharmacol Ther. 1996 Apr;59(4):469-75.		
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